

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

James D. McIninch

Appl. No. 09/698,213

Filed: October 30, 2000

For: **Computational Nucleic Acid
Coding and Feature Analysis**



Art Unit: 1631

Examiner: C. Smith

Atty. Docket: 16517.075

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Response to Office Action Mailed January 13, 2003 **TECH CENTER 1600/2900**

Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the Office Action mailed January 13, 2003 (Paper No. 18), Applicant submits the following Amendment and Remarks.

In the claims

Please cancel non-elected claims 17-40 without prejudice to or disclaimer of the underlying subject matter contained therein.

Remarks

Claims 1-44 were previously pending in the present application. Non-elected claims 17-40 have been cancelled without prejudice to or disclaimer of the underlying subject matter contained therein. Therefore, claims 1-16 and 41-44 are currently pending in this application.

Claim Rejection – 35 USC § 112, First Paragraph, written description

Claim 15 stands rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description support. Applicant respectfully disagrees.

The Examiner contends that the phrase "is about 75 to about 100 nucleotides" in claim 15 is not supported. Applicant first points out that the language quoted above by the Examiner is not the language that appears in pending claim 15. If instead the Examiner intended to assert that the phrase "is about 75 to about 125 nucleotides", which does appear in pending claim 15, is not adequately supported by the specification, then the Applicant directs the Examiner's attention to lines 1 and 2 of page 27 and originally filed claim 15, both of which clearly support the currently claimed window length. Applicant submits that this claim does not contain new matter and respectfully requests the Examiner to withdraw this rejection.

Claim Rejections – 35 USC § 112, First Paragraph, enablement

Claims 1-16 and 41-44 stand rejected under 35 U.S.C. 112, first paragraph, as allegedly not enabled. Applicant respectfully disagrees.

The Examiner argues that the cited claims are enabled to the extent of four equations given in the specification and four particular bias values but contends that the specification "does not reasonably provide enablement for any method of computation for determining the probabilities." Office Action at page 4.

Applicant strenuously disagrees with this rejection. The Applicant is under no obligation to provide within the confines of the specification *any* computational method that can be used to perform the method steps of the present invention. The enablement requirement is met if the description enables any mode of making and using the claimed invention. *Engel Industries, Inc. v. Lockformer Co.*, 946 F.2d 1528 (Fed. Cir. 1991). The Applicant has provided a working example within the specification, and the claim as written is therefore enabled. It is wrong as a matter of law for the Examiner to suggest that every possible permutation of computation must be specifically disclosed in the application.

Further, to the extent that computational methods already exist in the art, it is nonsensical to suggest that these methods are not enabled. If they exist and can be used with the present invention, they are *per se* enabled. One of ordinary skill in the art would be able to easily recognize which statistical computation methods could be used, and no "undue experimentation"

would be required to apply them to the present invention. To bolster her position, the Examiner claims that there exists an "unpredictability of generating probability values." Office Action at page 5. Applicant is at a loss to understand what exactly the Examiner finds unpredictable about the use of mathematical equations in the present invention. Applicant suggests that the current application does not entail plant transformation or other molecular processes. The present invention deals with the application of pure mathematics to statistically compute probability values. There is no unpredictability in this process. In essence, it is two plus two equals four.

Applicant additionally asserts that the Applicant is under no obligation to provide a laundry list of potentially useful computational techniques within the body of the specification. It is well established that the specification preferably omits what is known in art. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986). One of ordinary skill in the art, using the teachings of the specification, could readily substitute any appropriate computational method with the embodiments taught in the specification.

Finally, with reference to the full paragraph on page 5 of the office action beginning on line 6, Applicant questions whether the Examiner believes, while the Applicant does not, that the rejected claims are not enabled or whether she believes the rejected claims are overly broad. It is well settled that undue breadth and enablement are not to be equated. The Examiner contends in this paragraph that "[i]n order to broaden the scope of the instant invention the disclosures of such printed publications are essential material." Applicant again strenuously disagrees that the claims are either unduly broad or not enabled, and requests that the Examiner provide statutory or regulatory support for the proposition that prior art references need to be added to the specification verbatim to "broaden the scope of the instant invention" or enable the rejected claims. Applicant believes that this rejection is inappropriate. As such, an amendment to the disclosure or a submission of a declaration is unnecessary.

In light of the above, Applicant requests that this rejection be withdrawn.

Claim Rejections – 35 USC § 112, second paragraph

Claims 1-16 and 41-44 stand rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite. Applicant respectfully disagrees.

Claims 3 and 11 stand rejected under 35 U.S.C. § 112, second paragraph as indefinite because, the Examiner asserts, $\Phi(f)$ cancels itself out in each equation, thereby nullifying its effect on the equation. Office Action at page 6. Applicant is again at a loss to understand the rejection. One of ordinary skill in the art, in view of the disclosure, would not have any problem determining the scope of the claims containing the equation, even if the Examiner's contention were assumed to be true. This cannot be concluded to be indefinite.

Claims 1-16 and 41-44 stand rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite for a lack of antecedent basis for the phrase "said probability of said nucleic acid sequence," which appears in step d) or a similar antecedent issue. The antecedent basis for this is clearly set forth in step c), which determines "a probability for said nucleic acid sequence." If in step c) "a probability for said nucleic acid sequence" is referred to a first time, then a second reference is properly referred to as "said probability of said nucleic acid sequence." This is not indefinite.

Claims 1-16 and 41-44 stand rejected under 35 U.S.C. § 112, second paragraph as indefinite for their use of the phrase "based upon." Applicant disagrees that this phrase is indefinite because, as noted in a previous response, in light of the detailed computational methods given in the specification, one of ordinary skill in the art could readily assess how the determining in step d) is based upon the probability and the bias. Claims are not read in a vacuum. *In re Marosi*, 710 F.2d 799 (Fed. Cir. 1983).

Claim 7 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite for use of the word "capable." "Capable" is not indefinite because one of ordinary skill in the art could readily ascertain whether the "determining" step is capable of accepting a bias.

Claims 3 and 11 stand rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite for the use of f , S , P , P_i and Φ . Applicant again notes that the claims must be read in

light of the specification. The terms f , S , P , P_i and Φ are all clearly defined and used in the specification (see, for example, the Examples), and one of ordinary skill in the art would have no difficulty in determining their metes and bounds. The Examiner suggests on page 7 that the Applicant should list "in the claim the exact definition of each term." Once again, Applicant requests the Examiner provide the statutory or regulatory basis for this requirement.

Claims 8-16 and 44 stand rejected under 35 U.S.C. § 112, second paragraph as indefinite. One of ordinary skill in the art in light of the specification would find these claims and the use of "determining a probability for said window for each of said states" easily understandable in view of the specification.

In view of the above remarks, reconsideration and withdrawal of the Section 112, second paragraph rejections is respectfully requested.

Claim Rejections – 35 USC § 102

Claims 1, 4, 5, 7-9, 12, 13, 15, and 41-44 stand rejected under 35 U.S.C. 102(b) over Borodovsky. Applicant respectfully and strenuously disagrees.

In order for a reference to anticipate a claim under 35 U.C.S. 102(b), each and every element of that claim must appear in a single art reference. *PPG Industries, Inc. v. Guardian Industries Corp.*, 75 F.3d 1558 (Fed. Cir. 1996). Claims 1, 8, and 41-44 include the step of "determining a probability . . . based upon . . . a bias." Claim 7 includes the phrase, "capable of accepting a bias." The Examiner has not indicated where in Borodovsky this element of the rejected claim occurs, and, lacking such indication, Borodovsky cannot anticipate the claimed invention. That is, Borodovsky cannot be used as a reference to anticipate either a claim that bases a probability determination on a bias or a claim that includes an algorithm that is capable of accepting a bias when the Examiner has not indicated that Borodovsky even suggests the use of bias, much less discloses such use.

The Examiner does not reassert the previously submitted reason for this 102(b) rejection, and so Applicant believes it has been withdrawn. Instead, the Examiner now contends that $\Phi(f)$

cancels itself out in each equation given in claims 3 and 11, which leads to a conclusion that the equations in the present application are identical to those in Borodovsky.

This conclusion is wrong for at least two reasons. First, the expression $\Phi(f)$ does not appear in any of the rejected claims, and it is improper to read this limitation into those claims or to define "capable of accepting a bias" as anything containing the expression $\Phi(f)$. Second, as is clear from the specification, the equations presented in the present application are not equivalent to those in Borodovsky, and the working examples demonstrate the manifest effects of using a bias.

In light of the foregoing, Applicant requests that this rejection be withdrawn.

Supplemental Information Disclosure Statement

Applicant herewith submits copies of the supplemental information disclosure statement, 1449 form, and accompanying reference that were previously submitted on November 9, 2002. Applicant requests that the Examiner initial, sign, and return the 1449 form with her next action.

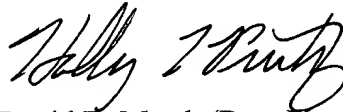
Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicant believes that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

In the event that extensions of time beyond those petitioned for herewith are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned. Applicant does not believe any additional fees are due in conjunction with this filing. However, if any fees under 37 C.F.R. 1.16 or 1.17 are required in the present application, including any fees for extensions of time, then the Commissioner is hereby

authorized to charge such fees to Arnold & Porter Deposit Account No. 50-2387, referencing matter number 16517.075.

Respectfully submitted,



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Date: February 27, 2003

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